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INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

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Applicant's or agent's file reference P566.PC.34	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/IB 03/04008	International filing date (day/month/year) 12.09.2003 ✓	Priority date (day/month/year) 16.09.2002 ✓
International Patent Classification (IPC) or both national classification and IPC A61B17/16		
Applicant PRECIMED S.A. et al. ✓		

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- This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
- This REPORT consists of a total of 7 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
 These annexes consist of a total of 1 sheets.

- This report contains indications relating to the following items:
 - I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 18.03.2004 ✓	Date of completion of this report 22.12.2004
Name and mailing address of the International preliminary examining authority:  European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Nice, P Telephone No. +31 70 340-2354 

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/IB 03/04008**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-6 as originally filed

Claims, Numbers

1-9 as originally filed

10-13 received on 26.11.2004 with letter of 26.11.2004

Drawings, Sheets

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).
(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	3-5,8,10-11
	No: Claims	1-2,6-7,9,12
Inventive step (IS)	Yes: Claims	3-5,8
	No: Claims	1-2,6-7,9-13
Industrial applicability (IA)	Yes: Claims	1-13
	No: Claims	

2. Citations and explanations

see separate sheet

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Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1 Reference is made to the following documents:

D1: DE-A-19532898

D2: US-A-4023572

D3: US-A-5176711

D4: US-A-5658290

D5: EP-A-1066796

2 D1 discloses :

An acetabular reamer for surgical use, the reamer comprising

(a) a substantially hemispherical, hollow dome defining an equatorial plane and an apex, and

(b) a reamer spindle interface structure fixedly attached to the inside of the dome so as to substantially inset the interface structure within the dome

See D1, column 6, lines 16-17 and figure 21. This figure shows that the end of the spindle is attached to the dome ("fixedly attached" does not clearly differ in meaning from "attached"), on its inside. The point of attachment is at the top of the dome i.e. as inset as it could possibly be and hence meeting any definition of "substantially inset". Wherever two elements, in this case the reamer and the dome, are attached to each other there are ipso facto "interface structures" on each of them unless it is clear that this expression means something more than simply the parts of the two elements which contact each other, which is not the case in claim 1.

"in order to help minimize the size of an assembly of the reamer and a reamer spindle when performing joint surgery" (claim 1) is not a feature of the claimed subject-matter, but is rather a statement of the problem which the claimed subject-matter is intended to solve. Hence D1 discloses all the features of claim 1, whose subject matter is therefore not new in the sense of Article 33(2) PCT.

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- 3 The expression "substantially inset" used in claim 1 is vague and unclear and leaves the reader in doubt as to the meaning of the technical feature to which it refers, thereby rendering the definition of the subject-matter of said claim unclear (Article 6 PCT). Even considering the specification, no clear definition of the expression can be obtained. Page 1, second paragraph can be taken to suggest that a "substantial inset" is one which "minimizes the size of the reamer and the reamer coupling assembly". This however would be contradictory since a *minimum* is a single value, whereas *substantial* covers a range of values, so a *substantial* inset cannot correspond to a *minimum* size.

Lacking a definition of "substantially inset", any inset can be taken to be substantial; after all, any inset will reduce impingement on the femoral bone and the size of the necessary incision, the criteria stated at page 2 lines 15-16 of the description, relative to a reamer in which there is no inset.

D2 discloses (the references in parentheses applying to this document):

An acetabular reamer for surgical use, the reamer comprising
(a) a substantially hemispherical, hollow dome (101) defining an equatorial plane and an apex, and
(b) a reamer spindle interface structure (110) fixedly attached to the inside of the dome so as to inset - and hence substantially inset - the interface structure within the dome
(see D2, column 5, lines 42-46 and figure 1).

The subject matter of claim 1 is therefore not new in the sense of Article 33(2) PCT by comparison with the prior art of D2.

- 4 Document D1, which is considered to represent the most relevant state of the art for claim 13, discloses a hollow reamer having a substantially inset interface structure. From this, the subject matter of claim 13 differs in that the reamer is attached to the coupling of an angled reamer spindle via the inset interface structure. This solves the problem of providing for minimum invasiveness of orthopedic surgery. It can however be seen that in D3 (see figures 7c-e thereof) the use of an angled reamer spindle permits all reaming to be carried out via the same approach (compare the positions of the shaft of reamer (128) in figure 7c and of shaft (140) in figures 7d-e), i.e. it

provides for minimum invasiveness, so it

would be obvious to the skilled practitioner to adopt an angled reamer spindle with the reamer of D1 in order to solve the problem.

The subject matter of claim 13 therefore cannot be considered as involving an inventive step (Article 33(3) PCT).

- 5 Dependent claims 2, 6-7 and 9-12 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, the reasons being as follows:
 - 5.1 The reamer of D1 has the features of claim 2. Where there is attachment, there are necessarily not only interface structures but also a junction ("internal junction" does not in this context have a clearly different meaning from "junction"). The reamer of D1 also has the features of claims 6-7 (the reamer shaft in D1 is shown as a simple cylinder directly attached to the apex of the reamer shell; those regions of the circumference of the cylinder which are attached to the apex can be considered to form part of an interface structure in whose latitudinal plane they lie).
 - 5.2 The reamer of D2 also has the features of claim 2, and in addition those of claims 9 and 12 (see D2 figures 18-19).
 - 5.3 An interface comprised of two or more cross-bars (claim 10) is a commonly-used alternative in the acetabular reamer art to the single bar shown in D2, see for example D4 figure 1 .
 - 5.4 Placing a centering boss at the centre of a reamer's single cross bar (claim 11) is also well-known in the art, see for example D5 figure 1 (feature 134).
- 6 The subject matter of claims 3-5 and 8 (NB claims 4-5 and 8 all include all the features of claim 3 and should therefore be dependent on claim 3) differs from the prior art of D1 in that a section of the dome has been removed to reduce the static profile compared to the dynamic profile. The subject-matter of these claims is therefore novel (Article 33(2) PCT).

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Moreover this solution to the problem of reducing the size of incision required, in order to achieve minimally invasive surgery, is not obvious, because no reaming equipment with such a section removed is known in a field related to acetabular preparation. The subject matter of claims 3-5 and 8 is therefore considered as involving an inventive step (Article 33(3) PCT).

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1 10. The reamer of claim 1, wherein the interface structure comprises at least two, equally spaced
2 apart cross bars.

1

1 11. The reamer of claim 1 wherein the interface structure is fixedly attached to the inside of the
2 dome by a single cross bar having a central centering boss.

1

1 12. The reamer of claim 1 wherein the interface structure is fixed to the inside of the dome by a
2 single cross bar having a central centering hole.

1

1 13. A surgical reamer assembly comprised of

2 (a) a hollow reamer having a substantially inset interface structure, and

3 (b) an angled reamer spindle having a coupling, wherein the reamer and the spindle are attached
4 together via the inset interface structure and the coupling, the assembly providing for minimum

5 invasiveness of orthopedic surgery.

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